

## **DETAILED ACTION**

The receipt is acknowledged of applicants' request for pre-appeal review filed 07/06/2009.

Claims 55-65, 67-93 are pending.

Claims 69-92, 94-96 are withdrawn as being directed to a nonelected invention. Election was made without traverse in the reply filed 02/28/2002.

Claims 55-65, 67, 68 and 93 are included in the prosecution.

**The finality of the office action mailed 01/05/2009 has been withdrawn, and new office action on the merit is hereby issued.**

### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 55-65, 67, 68 and 93 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The limitation "90% of the water

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soluble peptide are between 300 and about 1300 Dalton in molecular weight" as recited by claim 55 is confusing. The 90% fraction of soluble peptides having 300-1300 Dalton molecular weight is not claimed as the soluble peptides included in the claimed composition. It is not clear from the claim if the soluble peptides included in the claimed composition are chosen from the 90% fraction having molecular weight between 300 and 1300 Dalton, or chosen from the 10% having other molecular weights! Further, claim 55 recites "the precipitate comprises water soluble peptide", and with the "comprising" recitation it is difficult to determine which fraction of peptide included in the claimed composition? Is it the 90% fraction having 300-1300 molecular weight or is it the 10% fraction having other molecular weights? In other words, does the claimed composition contain 90% of soluble peptide, or the process yields composition having 90% low molecular weight peptides? In the later case, the composition will have 10% peptides having mixture of other molecular weights. The expression "composition comprising" could read on the 90% peptides having low molecular weights as well as read on the 10% of peptides that may not have the low molecular weight. The composition as recited by the claims does not define which peptide is in the composition, or reciting that the low molecular weight peptides produced by the process is those used in the composition.

The term "at least about" as recited by claim 55 does not set forth the meets and bounds of the claim. Recourse to the specification, does not define the term. "At least 90%" requires 90% and more and does not read on amounts less than 90%. To the

contrary, "about" permits amounts below 90%. In determining the range encompassed by the term "about", one must consider the context of the term as it is used in the specification and claims of the application. The court held that claims reciting "at least about" were invalid for indefiniteness where there was close prior art and there was nothing in the specification, prosecution history, or the prior art to provide any indication as to what range of specific activity is covered by the term "about." *Amgen, Inc. v. Chugai Pharmaceutical Co.*, 927 F.2d 1200, 18 USPQ2d 1016 (Fed. Cir. 1991). See also *USA, Inc.*, 395 F.3d 1364, 1370, 73 USPQ2d 1641, 1646 (Fed. Cir. 2005), where the court held that patentee failed to redefine the ordinary meaning of "about" to mean "exactly" in clear enough terms to justify the counterintuitive definition of "about."

### ***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 55 and 67 are rejected under 35 U.S.C. 102(b) as being anticipated by JP publication 1988-2002582 ('582), provided by applicant in IDS 01/08/2004.

Claim 55 is directed to composition comprising water soluble peptide, and wherein at least about 90% of said water soluble peptides are between about 300 and about 1300 daltons in molecular weight. The present claims are directed to product by

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process, and steps of obtaining the product do not impart patentability to the claims, absent evidence to the contrary.

JP '528 disclosed water soluble keratin protein and method of its production comprising degradation of body hair, horn, nails, hoofs, wool or feathers to the desired molecular weight appropriate for the purpose of use such as in cosmetics (first page, second page, last two paragraphs). The process of making the soluble keratin included the steps of decomposition of the peptides bonds in the keratin using oxidative hydrolysis, neutralization, washing, drying and filtration (forth page of the publication, and examples 1-3). Examples 1 and 3 show the keratin protein produced is made of soluble keratin having molecular weight of 1000, and example 2 shows the keratin protein produced is made of soluble keratin having molecular weight of 400. Examples show the product of degradation of keratin is wholly made of soluble keratin having low molecular weight, i.e. 100%, which read on "at least about 90%" soluble keratin. The reference disclosed regulating the molecular weight of the produced water soluble keratin by controlling the process conditions such as temperature, time, etc. (third page). If molecular weight of 1000 can be produced and 400 can be produced, then any molecular weight in between can also be produced including 850 claimed by claim 67.

### ***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 55-65, 67, 68 and 93 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP publication 1988-2002582 ('582), provided by applicant in IDS 01/08/2004, combined with GB 692,478 ('478) provided by applicant in IDS filed 05/02/2006.

### **Applicant Claims**

Applicants' claims are directed to a composition comprising water soluble peptides, wherein said peptides are obtained by:

oxidizing human or animal hair, human or animal nails, fur, hooves, or feathers, in an aqueous oxidizing solution;

filtering said aqueous oxidizing solution to obtain a water soluble portion;

substantially neutralizing said water soluble portion; and

adding a water-miscible organic solvent to said water soluble portion, such that a precipitate is formed;

wherein said precipitate comprises water soluble peptides; and further wherein at least about 90% of said water soluble peptides are between about 300 and about 1300 daltons in molecular weight.

### **Determination of the Scope and Content of the Prior Art (MPEP §2141.01)**

JP '528 teaches water soluble keratin protein and method of its production comprising degradation of body hair, horn, nails, hoofs, wool or feathers to the desired molecular weight appropriate for the purpose of use such as in cosmetics (first page, second page, last two paragraphs). The process of making the soluble keratin included the steps of decomposition of the peptides bonds in the keratin using oxidative hydrolysis, neutralization, washing, drying and filtration (forth page of the publication, and examples 1-3). Examples 1 and 3 show the keratin protein produced is made of

soluble keratin having molecular weight of 1000, and example 2 shows the keratin protein produced is made of soluble keratin having molecular weight of 400. Examples show the product of degradation of keratin is wholly made of soluble keratin having low molecular weight, i.e. 100%, which read on "at least about 90%" soluble keratin. The reference teaches regulating the molecular weight of the produced water soluble keratin by controlling the process conditions such as temperature, time, etc. (third page). If molecular weight of 1000 can be produced and 400 can be produced, then any molecular weight in between are also produced including 850 claimed by claim 67.

**Ascertainment of the Difference Between Scope the Prior Art and the Claims  
(MPEP §2141.012)**

The present claims are directed to product by process, and steps of obtaining the product do not impart patentability to the claims, absent evidence to the contrary.

Although the reference suggested oxidative degradation and washing of the degraded keratin, however, does not explicitly exemplify oxidative degradation or teach the specific oxidizing agents and their amount as claimed by claims 55, 57, 58 and 65, or specific water miscible organic solvents as claimed by claims 55, 59-64. The reference does not teach the amount of sulfur in the water soluble peptide as claimed by claim 68. Although the reference teaches concentration and drying that may suggests powdering of the product, however, the reference does not explicitly teach powder form as claimed by claims 56 and 93.

GB '478 teaches the use of aqueous solution of peracetic acid for oxidizing wool to obtain soluble keratin that is not colored and suitable for more purposes, and further teaches that peracetic acid is preferred oxidizing agent because it is stable in its aqueous solution and not expensive (page 1, lines 40-46, 66-70; page 3, lines 1-9, 29-33, 67-70). GB '478 further teaches the steps of neutralization, filtering and drying (page 2, lines 125-130), and teaches precipitation of the keratin by water miscible alcohol or ketone to obtain powder that is then washed and dried (page 2, lines 38-42; page 4, lines 10-13).

**Finding of Prima Facie Obviousness Rational and Motivation**  
**(MPEP §2142-2143)**

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide cosmetic composition comprising water soluble keratin that has been produced by degradation of keratinous material using oxidizing agent as taught by JP '582, and use peracetic acid as an oxidizing agent and water-miscible organic solvent to precipitate keratin powder as taught by GB '478. One would have been motivated to do so because GB teaches that peracetic acid is preferred oxidizing agent because it is stable in its aqueous solution and not expensive, and because the reference further teaches that the powdered precipitated by water-miscible organic solvent is not discolored and useful for more purposes. One would reasonably expect formulating cosmetic composition comprising colorless water soluble keratin powder that has been produced by degradation of keratinous material using aqueous



solution of peracetic acid that is stable allowing applying the desired time for degradation of the keratinous material and meanwhile affordable.

Regarding the claimed amounts of oxidizing agent as claimed by claim 58 and the ratio and amounts of organic solvent and aqueous solution as claimed by claims 62-64, and the amount of sulfur in the soluble peptides as claimed by claim 68, JP '582 teaches adjustment the conditions of the process to obtain the desired degradation and consequently the desired molecular weight suitable for the intended use.

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis A. Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on (571) 272-0614. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

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Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free).

/Isis A Ghali/

Primary Examiner, Art Unit 1611

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